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Certification body of management systems

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

Certificate EN ISO 13485:2016

Quality management system certification

Certificate number: **QM30 0085 2019 0134**
Related initial audit report: **AQM 20190134 01**



Certificate holder: **ENGIMPLAN – Engenharia de Implantes
Indústria e Comércio Ltda.**

Rodovia Washington Luiz, Km 172 S/N – Jardim
Anhanguera – Condomínio Industrial Conpark,
Rio Claro 13.501-600, Brazil

The certificate was issued with respect to following scope:

**Project and development, manufacture, sales and post-sales
surveillance of orthopaedic implants, sterile and non-sterile, for
osteosynthesis and arthroplasty and their instrument sets**



Digitally
signed by
Radovan Máčaj

Radovan Macaj
Head of Certification body of management systems

Effective from: **01.12.2019**

Valid until: **30.11.2021**

bqs. issued the certificate on the basis of performed assessment of the quality management system in accordance with the harmonised standard EN ISO 13485:2016 and according to the requirements for certification bodies providing audit and certification of management systems, laid down by ISO/IEC 17021-1:2015. The certified quality management system is subjected to periodical surveillance performed by bqs. auditors and technical experts. Please see also notes overleaf.



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Additional information on certification under EN ISO 13485:2016

Related to certificate number:
QM30 0085 2019 0134



Description of products/services within the certification scope:

Sterile and non-sterile orthopaedic implants and their instrument sets

Types/Categories/Models: -

Facilities within the scope:

**ENGIMPLAN – Engenharia de
Implantes Indústria e Comércio Ltda.**

Rodovia Washington Luiz, Km 172 S/N –
Jardim Anhanguera – Condomínio Industrial
Conpark, Rio Claro 13.501-600, Brazil



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